IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

ALEAH HARRIS,	)	
	)	
Plaintiff,	)	
	)	CIVIL ACTION FILE
v.	)	
	)	NO. _____
C. R. BARD, INC. and	)	
AMERICAN MEDICAL SYSTEMS, INC.,	)	
	)	
Defendants.	)	
_____	)	

COMPLAINT

COMES NOW Aleah Harris as Plaintiff herein and hereby files this Complaint, showing the Court as follows:

PARTIES, JURISDICTION AND VENUE

1.

Plaintiff is a citizen of the State of Alabama.

2.

Defendant C. R. Bard, Inc. (“Bard”) is a New Jersey corporation with its principal place of business in New Jersey. All acts and omissions of Bard as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

3.

Defendant American Medical Systems, Inc. ("AMS) is a Delaware corporation with its principal place of business in Minnesota. All acts and omissions of American Medical Systems, Inc. as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

4.

Plaintiff is seeking damages in excess of $75,000.00. Subject matter jurisdiction is proper pursuant to 28 U.S.C. § 1332.

5.

Defendants have significant contacts with the Northern District of Georgia such that they are subject to personal jurisdiction within said district.

6.

Bard Medical Division (formerly Bard Urological Division), the division of Bard that designed, manufactured, marketed, packaged, labeled and sold the products at issue in this lawsuit, was and is located in the Northern District of Georgia in Covington, Georgia.

7.

This Court has personal jurisdiction over AMS under the Georgia Long Arm Statute. AMS routinely and systematically transacts business in Georgia, and has offices, agents and/or employees in Georgia. AMS has committed acts and consummated transactions in the State of Georgia from which it has derived and continues to derive substantial revenues, and it has otherwise committed purposeful actions in the State of Georgia which should have led it to reasonably anticipate being haled into court in Georgia.

8.

A substantial part of the events and omissions giving rise to Plaintiff's causes of action occurred in the Northern District of Georgia.

9.

Pursuant to 28 U.S.C. § 1391(a), venue is proper in the Northern District of Georgia.

FACTUAL BACKGROUND

10.

Plaintiff was implanted with the Avaulta Solo Anterior and Posterior Synthetic Support System and Monarc Subfascial Hammock (the "Products") during surgery performed by Dr. Carol Swindle at St. Vincent's Hospital in Birmingham, Alabama.

11.

The Products were implanted in Plaintiff to treat her pelvic organ prolapse and stress urinary incontinence, the uses for which the Products were designed, marketed and sold.

12.

As a result of having the Products implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, will likely undergo corrective surgery, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

13.

Bard designed, manufactured, marketed, packaged, labeled, and sold the Avaulta Solo Posterior Synthetic Support System, including that which was implanted in Plaintiff.

14.

AMS designed, manufactured, marketed, packaged, labeled, and sold the Monarc Subfascial Hammock, including that which was implanted in Plaintiff.

CAUSES OF ACTION

COUNT I: NEGLIGENCE

15.

Plaintiff incorporates by reference paragraphs 1-14 of this Complaint as if fully set forth herein.

16.

Defendants had a duty to individuals, including Plaintiff, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the Products.

17.

Defendants were negligent in failing to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the Products.

18.

As a direct and proximate result of Defendants' negligence, Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

19.

Plaintiff incorporates by reference paragraphs 1-14 of this Complaint as if fully set forth herein.

20.

The Products implanted in Plaintiff was not reasonably safe for their intended uses and were defective as a matter of law with respect to their design.

21.

As a direct and proximate result of the Products' aforementioned defects, Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

22.

Defendants are strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT

23.

Plaintiff incorporates by reference paragraphs 1-14 of this Complaint as if fully set forth herein.

24.

The Products implanted in Plaintiff were not reasonably safe for their intended uses and were defective as a matter of law with respect to their manufacture.

25.

As a direct and proximate result of the Products' aforementioned defects, Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

26.

Defendants are strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

COUNT IV: STRICT LIABILITY – FAILURE TO WARN

27.

Plaintiff incorporates by reference paragraphs 1-14 of this Complaint as if fully set forth herein.

28.

The Products implanted in Plaintiff were not reasonably safe for their intended uses and were defective as a matter of law due to their lack of appropriate and necessary warnings.

29.

As a direct and proximate result of the Products' aforementioned defects, Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

30.

Defendants are strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

COUNT V: BREACH OF EXPRESS WARRANTY

31.

Plaintiff incorporates by reference paragraphs 1-14 of this Complaint as if fully set forth herein.

32.

Defendants made assurances to the general public, hospitals and health care professionals that the Products were safe and reasonably fit for their intended purposes.

33.

Plaintiff and/or her health care provider chose the Products based upon Defendants' warranties and representations regarding the safety and fitness of the Products.

34.

Plaintiff, individually and/or by and through her physician, reasonably relied upon Defendants' express warranties and guarantees that the Products were safe, merchantable, and reasonably fit for their intended purposes.

35.

Defendants breached these express warranties because the Products implanted in Plaintiff were unreasonably dangerous and defective and not as Defendants had represented.

36.

Defendants' breaches of their express warranties resulted in the implantation of unreasonably dangerous and defective products in Plaintiff's body, placing Plaintiff's health and safety in jeopardy.

37.

As a direct and proximate result of Defendants' breaches of the aforementioned express warranties, Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

COUNT VI: BREACH OF IMPLIED WARRANTY

38.

Plaintiff incorporates by reference paragraphs 1-14 of this Complaint as if fully set forth herein.

39.

Defendants impliedly warranted that the Products were merchantable and were fit for the ordinary purposes for which they were intended.

40.

When the Products were implanted in Plaintiff to treat her pelvic organ prolapse, the Products were being used for the ordinary purposes for which they were intended.

41.

Plaintiff, individually and/or by and through her physician, relied upon Defendants' implied warranties of merchantability in consenting to have the Products implanted in her.

42.

Defendants breached these implied warranties of merchantability because the Products implanted in Plaintiff were neither merchantable nor suited for their intended uses as warranted.

43.

Defendants' breaches of their implied warranties resulted in the implantation of unreasonably dangerous and defective products in Plaintiff's body, placing Plaintiff's health and safety in jeopardy.

44.

As a direct and proximate result of Defendants' breaches of the aforementioned implied warranties, Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

COUNT VII: PUNITIVE DAMAGES

45.

Plaintiff incorporates by reference paragraphs 1-44 of this Complaint as if fully set forth herein.

46.

Defendants knew or should have known that the Products were defective and presented unreasonable risks of harm to Plaintiff.

47.

Defendants sold the Products to Plaintiff's health care providers and other health care providers in Georgia and

throughout the United States without doing adequate testing to ensure that the Products were reasonably safe for implantation in the female pelvic area.

48.

Defendants sold the Products to Plaintiff's health care providers and other health care providers in Georgia and throughout the United States without doing adequate testing to determine whether the Products degraded in vivo. The Products do, in fact, degrade in vivo, which causes the severe and debilitating injuries suffered by Plaintiff and numerous other women.

49.

Defendants ignored reports from health care providers throughout the United States of the Products' failures to perform as intended, which lead to the severe and debilitating injuries suffered by Plaintiff and numerous other women. Rather than doing adequate testing to rule out the Products' designs or the processes by which the Products are manufactured as the cause of these severe and debilitating injuries, Defendants chose instead to instruct their sales forces to downplay the Products' risks, and have continued to market and sell the Products as safe and effective.

50.

Defendants' conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiff demands a trial by jury, judgment against Defendants, jointly and severally, for compensatory and punitive damages in an amount exceeding $75,000, as well as costs, attorney fees, interest, or any other relief, monetary or equitable, to which she is entitled.

PLAINTIFF DEMANDS A TRIAL BY JURY.

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